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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,883	04/13/2004	Kenneth Merdan	1001.1748101	4001

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EXAMINER	
ELVE, MARIA ALEXANDRA	

ART UNIT	PAPER NUMBER
3742	

MAIL DATE	DELIVERY MODE
08/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,883	MERDAN ET AL.	
	Examiner	Art Unit	
	M. Alexandra Elve	3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-8,10-19 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-8,10-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 7-8 & 10-17, 19 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acciai et al. (USPN 5,855,802) in view of Pacetti et al. (USPN 6,695,920), McCoy (USPAP 2003/0234243 A1) and Applicant's Admitted Prior Art (AAPA).

Acciai et al. discloses a method and apparatus for forming a tubular article having a perforated annular wall, such as a surgical stent. Figure 3 shows a laser (40), a fiber optic (44), a beam splitter (42) and an optical guide (46). Note that the laser beam moves partially in a horizontal direction in the fiber optic and horizontally in the optical guide. The tubular member (32) is mounted in a chuck (34). The laser beams are focused by focusing mirrors (56 & 58) mounted at 45° (tuning mirror). The apparatus is supported by a precision table (66) and a table (68). The tubular member is rotated by a rotating means (36), powered by a rotary drive motor (38). The tubular member is moved in a horizontal (translational) direction by means of a linear drive motor (70). The laser beams (60 & 62) cut the tubular member, in this case a stent.

Acciai et al. does not teach all the elements mounted to one table, the coupling of the linear and rotary motors, the presence of guides, the workpiece below the motor(s), the direct cutting using the laser, or the use of a coolant.

Pacetti et al. discloses a mandrel apparatus for supporting a stent. The stent is connected to a rotational motor (24) and another motor (28), which provides linear directional motion (back and forth along a rail). In addition, gears members (22) (guides) and a rail (30) provide guide members.

It would have been obvious to one of ordinary skill in the art at the time of the invention to couple the motor(s) and provide guides (gear members for stent support and rails), as taught by Pacetti et al. in the Acciai et al. system because coupling the motors minimizes manufacturing real estate and guides support components and provides articles for motion.

McCoy discloses a multi-axis laser apparatus for the fine cutting of tubing (i.e. the making of stents). Tubes are affixed under a laser and positioned using a computer-generated signal in order to move the tube in a very intricate and precise pattern around a linear and rotary axis. A water system is incorporated in the apparatus to remove debris falling into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. The tubing is feed by reciprocal relative movement through a cutting block by a collet relative to the clamp, which positions a finite length of the tubing beneath the beam. The pattern cut is controlled by movement of the tubing relative to the beam simultaneously along an X (length) and Y axis (rotary) controlled by a computerized encoder as part of

a CNC positioning equipment. A computer software controlled rotary and linear movement subassembly apparatus. The cutting of the tubing is conducted on an x-axis table, which has a combination of rotary (y-axis) and linear (x-axis) movements of the tubing relative to the cutting laser beam. (abstract, figures, 0017, 0019, 0025, 0028, 0033)

McCoy discloses:

> The present invention provides an improved system for producing metal stents with a fine precision structure cut from a small diameter, thin-walled, cylindrical tube. The tubes are fixtured under a laser and positioned utilizing a computer generated signal to move the tube in a very intricate and precise pattern around a linear and rotary axis. The stent is cut from small diameter tubing held between a collet and clamp, one of which is periodically opened and the other reciprocably moved to position a small length of tubing, sequentially beneath the cutting head. A water system is incorporated in the apparatus to remove debris falling into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. (abstract)

> …a gas jet stream substantially surrounds the laser beam where the beam impinges on the working outer tube surface to aid in cutting said tubing. (claim 7)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a laser directly and use a coolant as taught by McCoy in the Acciai et al. apparatus and process because direct laser cutting while enhance efficiency and the coolant would yield greater precision because the debris would be removed during the laser machining.

Making elements integral was held to have been obvious. In re Wolfe 116 USPQ 443. Reversal of parts was held to have been obvious. In re Gazda 104 USPQ 400. Rearrangement of parts was held to have been obvious. In re Japikse 86 USPQ 70.

AAPA includes a description of a laser/water jet hybrid made by SYNOVA Inc. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the SYNOVA hybrid laser/water system because it would ensure precision machining of the stent by removing cutting debris.

Claims 1, 5, 7-8 & 10-17, 19 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acciai et al. (USPN 5,855,802) in view of Pacetti et al. (USPN 6,695,920), McCoy (USPAP 2003/0234243 A1) and Kranz (USPN 6,197,047).

Acciai et al. discloses a method and apparatus for forming a tubular article having a perforated annular wall, such as a surgical stent. Figure 3 shows a laser (40), a fiber optic (44), a beam splitter (42) and an optical guide (46). Note that the laser beam moves partially in a horizontal direction in the fiber optic and horizontally in the optical guide. The tubular member (32) is mounted in a chuck (34). The laser beams are focused by focusing mirrors (56 & 58) mounted at 45° (tuning mirror). The apparatus is supported by a precision table (66) and a table (68). The tubular member is rotated by a rotating means (36), powered by a rotary drive motor (38). The tubular member is moved in a horizontal (translational) direction by means of a linear drive motor (70). The laser beams (60 & 62) cut the tubular member, in this case a stent.

Acciai et al. does not teach all the elements mounted to one table, the coupling of the linear and rotary motors, the presence of guides, the workpiece below the motor(s), the direct cutting using the laser, or the use of a coolant.

Pacetti et al. discloses a mandrel apparatus for supporting a stent. The stent is connected to a rotational motor (24) and another motor (28), which provides linear directional motion (back and forth along a rail). In addition, gears members (22) (guides) and a rail (30) provide guide members.

It would have been obvious to one of ordinary skill in the art at the time of the invention to couple the motor(s) and provide guides (gear members for stent support and rails), as taught by Pacetti et al. in the Acciai et al. system because coupling the motors minimizes manufacturing real estate and guides support components and provides articles for motion.

McCoy discloses a multi-axis laser apparatus for the fine cutting of tubing (i.e. the making of stents). Tubes are affixed under a laser and positioned using a computer-generated signal in order to move the tube in a very intricate and precise pattern around a linear and rotary axis. A water system is incorporated in the apparatus to remove debris falling into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. The tubing is feed by reciprocal relative movement through a cutting block by a collet relative to the clamp, which positions a finite length of the tubing beneath the beam. The pattern cut is controlled by movement of the tubing relative to the beam simultaneously along an X (length) and Y axis (rotary) controlled by a computerized encoder as part of

a CNC positioning equipment. A computer software controlled rotary and linear movement subassembly apparatus. The cutting of the tubing is conducted on an x-axis table, which has a combination of rotary (y-axis) and linear (x-axis) movements of the tubing relative to the cutting laser beam. (abstract, figures, 0017, 0019, 0025, 0028, 0033)

McCoy discloses:

> The present invention provides an improved system for producing metal stents with a fine precision structure cut from a small diameter, thin-walled, cylindrical tube. The tubes are fixtured under a laser and positioned utilizing a computer generated signal to move the tube in a very intricate and precise pattern around a linear and rotary axis. The stent is cut from small diameter tubing held between a collet and clamp, one of which is periodically opened and the other reciprocably moved to position a small length of tubing, sequentially beneath the cutting head. A water system is incorporated in the apparatus to remove debris falling into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. (abstract)

> …a gas jet stream substantially surrounds the laser beam where the beam impinges on the working outer tube surface to aid in cutting said tubing. (claim 7)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a laser directly and use a coolant as taught by McCoy in the Acciai et al. apparatus and process because direct laser cutting while enhance efficiency and the coolant would yield greater precision because the debris would be removed during the laser machining.

Making elements integral was held to have been obvious. In re Wolfe 116 USPQ 443. Reversal of parts was held to have been obvious. In re Gazda 104 USPQ 400. Rearrangement of parts was held to have been obvious. In re Japikse 86 USPQ 70.

Acciai et al., Pacetti et al. and McCoy teach a laser and the use of water, but a water laser is not specifically taught.

Kranz discloses:

A stent…

In a preferred embodiment of a stent according to the invention the partition lines are of a width substantially corresponding to that of a clean incision when the surface is severed by means of a cutting beam, e.g. **a cutting jet of water preferably a laser beam.** Narrow partition lines give the non-expanded stent particularly high stability. (col. 2, lines 29-34)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a water/laser cutting jet as taught by Kranz in the Acciai et al. Pacetti et al. and McCoy apparatus and process because it would ensure precision machining of the stent by removing cutting debris.

Claims 6 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acciai et al., Pacetti et al., McCoy and (AAPA or Kranz), as stated above and further in view of Magnante (USPN 6,086,204)

Acciai et al., Pacetti et al. and McCoy teach a table/base, however, a granite base is not taught.

Magnante discloses:

…modified surfaces on contact lenses … three dimensional contour cutting, laser ablation… (abstract)

…Correcting Surfaces on Lenses…
… Since the machine must be completely free of both internal and external vibrations, both lathe 30 and x-z slides 32 are secured to a pneumatically isolated table top 35 which rests on **granite base** 36. (col. 15, lines 44-45, 67 & col. 16, lines 25-27)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a granite base as taught by Magnante in the Acciai et al. Pacetti et al. and McCoy apparatus and process because it would ensure precision machining of the stent.

The type of materials chosen is a choice in design and substitution of known equivalent structures (table for granite) has been held obvious. In re Kuhle 188 USPQ (CCPA 1975), In re Ruff 118 USPQ 343 (CCPA 1958).

Response to Arguments

Applicant's arguments filed 5/13/08 have been fully considered but they are not persuasive.

Applicant argues that Kranz does not teach a laser/water jet hybrid. The examiner respectfully notes that Kranz teaches a laser with water, used to cut stents,

much the same as instant claims. Additionally, Applicant's Admitted Prior Art discloses a laser/water jet hybrid system manufactured by SYNOVA Inc.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Alexandra Elve whose telephone number is 571-272-1173. The examiner can normally be reached on 7:30-4:00 Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tu B. Hoang can be reached on 571-272-4780. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 17, 2008.

/M. Alexandra Elve/
Primary Examiner, Art Unit 3742